Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2006 list were published in the Federal Register in December 2005.

New Approvals

NADA Number: 141-247

Trade Name:	Cydectin® Oral Drench for Sheep
Ingredients:	Moxidectin
Sponsor:	Fort Dodge Animal Health Division of Wyeth
Approval Date:	November 30, 2005
Status:	Over-the-counter
Route:	Oral
Species:	Ovine
Drug Form:	Liquid (solution)
Concentration:	1 milligram per milliliter
Indications:	For the treatment and control of the adult and larval (L_4) stages of the following internal parasites: *Haemonchus contortus* - Adult and L_4 larvae *Teladorsagia circumcincta* – Adult and L_4 larvae *Teladorsagia trifurcata* - Adult and L_4 larvae *Trichostrongylus axei* - Adult and L_4 larvae *Trichostrongylus colubriformis* - Adult and L_4 larvae *Trichostrongylus vitrinus* – Adult and L_4 larvae *Cooperia curticei* - Adult and L_4 larvae *Cooperia oncophora* – Adult and L_4 larvae *Oesophagostomum columbianum* - Adult and L_4 larvae *Oesophagostomum venulosum* – Adult and L_4 larvae *Nematodirus battus* - Adult and L_4 larvae *Nematodirus filicollis* - Adults and L_4 larvae *Nematodirus spathiger* - Adults and L_4 larvae
Patent number:	4,916,154 Expiration date: April 10, 2007
Tolerance:	*21CFR 556.426* Moxidectin: The tolerance for parent moxidectin (the marker residue) in sheep is 900 parts per billion in fat, 200 parts per billion in liver, and 50 parts per billion in muscle.
Withdrawal:	7 days - Do not use in female sheep providing milk for human consumption because a withholding time in milk has not been established for this product.
Exclusivity:	7 years

21CFR 520.1454 & 556.426

ANADA Number: 200-362

Pioneer Product:	095-184
Trade Name:	Priconazole™ Lotion 1% and Spray 1%
Ingredients:	Miconazole nitrate
Sponsor:	First Priority Inc.
Approval Date:	November 14, 2005
Status:	Prescription only
Route:	Topical
Species:	Dogs and cats
Drug Form:	Liquid (lotion and solution)
Concentration:	1%
Indications:	For the treatment of fungal infections caused by *Microsporum canis, Microsporum gypseum,* and *Trichophyton mentagrophytes.*

21CFR 524.1443

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: 200-376

Pioneer Product:	046-285
Trade Name:	Sulfamed-G™
Ingredients:	Sodium sulfadimethoxine
Sponsor:	Cross Vetpharm Group Ltd.
Approval Date:	November 14, 2005
Status:	Over-the-counter
Route:	Oral
Species:	Chickens (broiler and replacement), turkeys (meat producing), cattle (beef, dairy heifers and calves)
Drug Form:	Powder (soluble)
Concentration:	94.6 grams of sulfadimethoxine per 107 grams of powder
Indications:	**Chickens:** For the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza. **Turkeys:** For the treatment of disease outbreaks of coccidiosis and fowl cholera. **Cattle:** For the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.
Tolerance:	*21 CFR 556.640* Sulfadimethoxine: A tolerance of 0.1 part per million is established for negligible residues of sulfadimethoxine in uncooked edible tissues of chickens, turkeys, and cattle. A tolerance of 0.01 part per million is established for negligible residues of sulfadimethoxine in milk.
Withdrawal:	Chickens and turkeys – 5 days Cattle – 7 days

21CFR 520.2220a

ANADA Number: 200-373

Pioneer Product:	102-380
Trade Name:	Furosemide Syrup 1%
Ingredients:	Furosemide
Sponsor:	First Priority, Inc.
Approval Date:	November 18, 2005
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Liquid (syrup)
Concentration:	10 milligrams per milliliter
Indications:	A diuretic-saluretic for use alone or in combination with Furosemide Injection in the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

21CFR 520.1010

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-087

Trade Name:	Quest® Gel
Ingredients:	Moxidectin
Sponsor:	Fort Dodge Animal Health Division of Wyeth
Approval Date:	November 23, 2005

This application provides for the treatment and control of two additional species of small strongyles (*Cylicocyclus radiatus* and *Petrovinema poculatus*.) This approval qualifies for THREE years of marketing exclusivity beginning on the date of approval.

21CFR 520.1452

NADA Number: 141-216

Trade Name: Quest® Plus Gel
Ingredients: Moxidectin, praziquantel
Sponsor: Fort Dodge Animal Health Division of Wyeth
Approval Date: November 23, 2005

This application provides for the treatment and control of two additional species of small strongyles (*Cylicocyclus radiatus* and *Petrovinema poculatus.*) This approval qualifies for THREE years of marketing exclusivity beginning on the date of approval.

21CFR 520.1453

NADA Number: 140-929

Trade Name: Micotil® 300
Ingredients: Tilmicosin phosphate
Sponsor: Elanco Animal Health A Division of Eli Lilly & Co.
Approval Date: December 2, 2005

This application provides for the addition of user safety information to the product labeling relating to the mechanism of toxicity and medical intervention.

21CFR 522.2471

Change of Sponsor

NADA Number(s): 134-644, 139-472, 140-916, 141-011

From: Boehringer Ingelheim Vetmedica, Inc.
To: Novartis Animal Health US, Inc.

Drug labeler code: 058198

NADA Number(s): 065-150

From: Nylos Trading Co., Inc.
To: Pharmaceutical Ventures, Ltd.

Drug labeler code: 050057

Addition of Sponsor

Pharmaceutical Ventures, Ltd.
P.O. Box D1400
Pomona, NY 10970

Drug labeler code: 050057

Actions Taken by FDA Center for Veterinary Medicine

Withdrawal(s) of Approvals

The following sponsors have requested that FDA withdraw approval of the 15 NADAs listed because the products are no longer manufactured or marketed:

NADA Number	Tradename (ingredients)	Sponsor (Drug labeler code):
049-462	Rainbrook Broiler Premix No. 1 (amprolium, arsanilic acid, ethopabate, penicillin G procaine,streptomycin)	Stockton Hay & Grain Co. (036541)
091-646	Rainbow Broiler Base Concentrate (amprolium, bacitracin zinc, ethopabate)	Stockton Hay & Grain Co. (036541)
091-647	Rainbow Broiler Base Concentrate (amprolium, chlortetracycline, ethopabate)	Stockton Hay & Grain Co. (036541)
096-780	TYLAN 10; TYLAN 40 (tylosin)	J. & R. Specialty Supply Co. (049768)
096-837	M & M Tylosin Premix (tylosin)	M & M Livestock Products Co. (026282)
098-687	Hy-Test Hy-Boost TY 5 Medicated (tylosin)	Kerber Milling Co. (029341)
119-063	Pyrantel Tartrate Ton Pack (pyrantel tartrate)	Bioproducts, Inc. (051359)
129-161	Nutra-Blend TYLAN 10 Sulfa Premix (tylosin, sulfamethazine)	Nutra-Blend Corp. (050568)
129-395	HYGROMIX 0.6 Premix (hygromycin B)	I.M.S. Inc. (050639)
129-646	TYLAN 10 Sulfa-G (tylosin,, sulfamethazine)	I.M.S. Inc. (050639)
131-146	FLAVOMYCIN 0.4 (bambermycins)	Triple ``F'', Inc. (011490)
136-369	Custom Ban Wormer 9.6 (pyrantel tartrate)	South St. Paul Feeds, Inc. (001800)
136-384	Swine Wormer-BN BANMINTH (pyrantel tartrate)	Nutra-Blend Corp. (050568)
136-601	Swine Guard-BN (pyrantel tartrate)	I.M.S. Inc. (050639)
138-656	BN Wormer-19.2 BANMINTH Premix (pyrantel tartrate)	Farmland Industries, Inc. (021676)

Following the withdrawal of approval of these NADAs, Kerber Milling Co., M & M Livestock Products Co., Nutra-Blend Corp., and South St. Paul Feeds, Inc., are no longer sponsors of an approved application. Therefore, we are removing entries for these four sponsors from 21 CFR 510.600(c)

Notice(s)

The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 2006. During 1991, at the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. In its final report, one of the IOM's recommendations was for the agency to publish an annual tentative schedule of its meetings in the Federal Register. This publication implements the IOM's recommendation.

For further information contact: Theresa L. Green, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

The IOM, at the request of the Commissioner, undertook a study of the use of the FDA's advisory committees. In its final report in 1992, one of the IOM's recommendations was for FDA to adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the Federal Register; FDA has implemented this recommendation. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. Because the schedule is tentative, amendments to this notice will not be published in the Federal Register. However, changes to the schedule will be posted on the FDA advisory committees' Internet site located at http://www.fda.gov/oc/advisory/default.htm. FDA will continue to publish a Federal Register notice 15 days in advance of each upcoming advisory committee meeting, to announce the meeting (21 CFR 14.20).

You may also obtain up-to-date information by calling the Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). The Veterinary Medicine Advisory Committee tentative dates of meetings are scheduled for March 15 and October 16. The Advisory Committee 10-Digit Information Line Code is 3014512548.

The Food and Drug Administration (FDA) is reopening until January 27, 2006, the comment period for the proposed rule published in the Federal Register of September 27, 2005 (70 FR 56394), proposing implementing regulations for designation of new animal drugs for minor uses and minor species under section 573 of the Federal Food, Drug, and Cosmetic Act (the act). FDA is reopening the comment period to update comments and to receive any new information.

Submit written or electronic comments by January 27, 2006. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments
For further information contact: Andrew Beaulieu, Center for Veterinary Medicine (HFV-50), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9090, e-mail: Andrew.Beaulieu@fda.gov.

The Food and Drug Administration (FDA) is announcing a public meeting on the Animal Drug User Fee Act (ADUFA) to seek public comments relative to the program's overall performance and reauthorization as directed by Congress. The public meeting will be held on February 24, 2006, from 9 a.m. to 5 p.m. Requests to make a presentation at the meeting must be received by February 10, 2006. Written comments regarding this meeting may be made by March 26, 2006, to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments .

The meeting will be held at the DoubleTree Hotel, Plaza II and III, 1750 Rockville Pike, Rockville, MD 20852. Registration is not required to attend the meeting. Parking is limited, so we recommend arriving by subway (Metro rail) if possible. The DoubleTree Hotel is accessible from the Metro rail's red line at the Twinbrook station.

For further information contact: Aleta Sindelar, Center for Veterinary Medicine (CVM) (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9004, FAX: 240-276-9020, e-mail:asindela@cvm.fda.gov.